IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

TC HEARTLAND LLC,	
Plaintiff,	Civil Action No. 1:23-cv-00665-LCB
v.	JLW
SUSAN S. SCHIFFMAN,	JURY TRIAL DEMANDED
Defendant.	

PLAINTIFF TC HEARTLAND LLC'S SUR-REPLY IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS COMPLAINT

In her opening brief in support of her Rule 12(b)(6) motion to dismiss, Defendant Susan S. Schiffman submitted what her counsel represented to be 24 pages from a much longer petition submitted to the FDA in 1987. Mot. (Dkt. 16) at 8 & Zapadka Decl. (Dkt. 17) at ¶¶ 3-5. Schiffman argued that this snippet of extrinsic evidence compelled dismissal of Plaintiff TC Heartland LLC's lawsuit against her. Dkt. 16 at 8-9. In its opposition to the motion to dismiss, Heartland pointed out the many evidentiary, factual, and legal problems with this argument. Dkt. 20 at 5-9. In her reply brief, Schiffman doubles down on her strategy of invoking dubious extrinsic evidence to justify dismissal of this case. She first tries to rehabilitate her citation to the 1987 petition excerpt by submitting a new declaration from her counsel, rife with yet more evidentiary, factual, and legal problems. Schiffman then cites—for the first time—two other pieces of improper extrinsic evidence.

This sur-reply brief addresses two limited areas: evidentiary and factual problems in Schiffman's new arguments in reply about the 1987 petition excerpt, and Schiffman's attempt to invoke in her reply brief two additional pieces of extrinsic evidence in support of her motion to dismiss (the "2021 Study" and the "'480 Patent"). Of course, if the Court has questions about any of the legal or factual issues already covered by the parties' prior briefing, Heartland stands ready to address any such questions at the Court's convenience.

The 1987 FDA Petition Excerpt. The only piece of extrinsic evidence Schiffman invoked in her opening brief in support of dismissal was what she alleged to be an excerpt of a 1987 petition submitted to the FDA for approval of sucralose as a food additive. In addition to noting that a petition from 1987 cannot possibly be dispositive of the composition of Splenda-brand sucralose 35 years later, Dkt. 20 at 9, Heartland pointed out in opposition that Schiffman failed to establish the authenticity of the excerpt, as required for the Court to take judicial notice of an extrinsic document submitted in support of a motion to dismiss under Rule 12(b)(6), *id.* at 6-7.

In her reply, Schiffman tries to overcome the authenticity issues raised by Heartland by submitting a new declaration from her counsel. Schiffman's counsel now says that the excerpt came from material produced by the FDA in response to Schiffman's *own* FOIA request. Dkt. 21-1 at \P 3. But that new assertion does not solve Schiffman's evidentiary problem. Schiffman still has submitted only a very small snippet of a more-than-20,000-page application, and Heartland still has had no opportunity at the motion to dismiss stage to verify the statements in either of her counsel's declarations.

In an attempt to convince the Court to consider the petition excerpt notwithstanding the evidentiary problems, Schiffman's reply also repeatedly misattributes the authorship of the petition. On the one hand, she characterizes it as "Tate & Lyle's (Splenda's exclusive manufacturer) food additive petition." Dkt. 21 at 3. On the other hand, she refers to it throughout her reply as the "TCH Petition"—*i.e.*, TC Heartland Petition. *See, e.g.*, *id.* at 3-5; *see also id.* at 3 ("Counts 1-4 Fail Because the Allegations in the Complaint are Directly Contradicted by Documents Submitted *by Heartland* to the FDA" (emphasis added)). Setting aside the internal inconsistency, both assertions are inaccurate. As Schiffman knows, the petition's author was neither Tate & Lyle nor Heartland, which has produced Splenda only since 2015, nearly thirty years after the petition was submitted. Rather, a separate company known as McNeil Specialty Products Company submitted the 1987 petition. Dkt. 17-8 at 4 (article published by Schiffman attributing the 1987 petition to "McNeil Specialty Products Company"); Dkt. 20 at 3.

In yet one final attempt to convince the Court to consider the petition excerpt notwithstanding the evidentiary problems, Schiffman claims for the first time in her reply that Heartland's website "relies upon" the 1987 petition. Dkt. 21 at 3-4 (asserting that the petition contains "data" that "Heartland relies upon on its website"). The website is extrinsic material, again, not properly considered on a motion to dismiss. In any event, if the Court wishes to read through the entire lengthy webpage cited by Schiffman, *but see Reid v. Charlotte-Mecklenburg Bd. of Educ.*, 2016 WL 4084039, at *19 (W.D.N.C. July 29, 2016), *aff'd sub nom. Reid v. Charlotte Mecklenburg Sch.*, 675 F. App'x 315 (4th Cir. 2017) (rejecting party's "bare citation to exhibits" without explanation or argument of

"exhibits' relevancy to his claims"), the Court will see that Heartland does not so much as mention this petition, let alone in any of the sections debunking Schiffman's false claim that Splenda contains S6A. Schiffman also claims, again for the first time, that the petition "is the very document that authorizes the marketing of Splenda-branded sucralose," Dkt. 21 at 3-4, but she fails to provide any support for that *ipse dixit* assertion.

For all these reasons, and the reasons explained in Heartland's opposition, the purported excerpt from the 1987 FDA petition cannot provide the basis for a Rule 12(b)(6) dismissal of Heartland's claims.

The "2021 Study." In her reply brief, Schiffman claims for the first time that a "2021 study" "tested Splenda-branded sucralose and found S6A." Dkt. 21 at 4. Schiffman makes this claim in a section of her reply brief titled "Counts 1-4 Fail Because the Allegations in the Complaint are Directly Contradicted by Documents Submitted by Heartland to the FDA," but she does not appear to be arguing that the "2021 study" was "submitted by Heartland to the FDA" (it was not). Rather, she appears to be suggesting that because her "opinions" about Splenda and S6A are based in part on this "2021 study," those "opinions" are immune from potential defamation liability. This argument, made for the first time in her reply, fails for numerous reasons.

For starters, Schiffman does not even try to argue that the "2021 study" is the kind of extrinsic evidence that a court could consider at the motion to dismiss stage. It is not.

Moreover, Schiffman does not even attach this "study" to her reply. Instead, she asks the Court to take her word for it that this study "tested Splenda-branded sucralose and found S6A." Dkt. 21 at 4. Even if Schiffman had tried to introduce this "study" into the

¹ Although Schiffman's reply also references "other publications," Dkt. 21 at 4, those publications generally relate to the alleged harms arising from consumption of sucralose or the metabolism of sucralose, not the presence of S6A in Splenda. As such, those "other publications" have no relevance to the core falsehoods at issue in Heartland's complaint. Schiffman's vague gestures toward these "other publications" are certainly not sufficient to compel dismissal of Heartland's complaint under Rule 12(b)(6).

record, the Court would have no basis, at the motion to dismiss stage, for crediting anything in the "study" over the well-pled allegations of the complaint. But Schiffman's conclusory description of this "study" in her reply brief does not even qualify as extrinsic evidence; it is not evidence at all. The Court should disregard it entirely.

Finally, even if Schiffman had attached this "study" to her reply brief; and even if this "study" said what she now claims it says about Splenda-branded sucralose; and even if the Court, at the motion to dismiss stage, could credit such a claim despite the well-pled allegations of the complaint; that would *still* not support dismissal. Schiffman appears to be arguing that, because she purportedly relied on this "study" for her "opinions," she is immune from any potential defamation liability. But the "2021 study" appears to be an unpublished "analysis" that is not publicly available and has never been subject to scrutiny by the scientific community. Dkt. 17-8 at 36. Even if Schiffman were correct that statements based on scientific opinions are immune from defamation liability (she is not), she cannot extend that argument to opinions based solely on unpublished, unreviewed, and unavailable material, for the reasons explained in Heartland's opposition brief. Dkt. 20 at 11-14. Further, when one implies that her opinions are "based upon facts which justify the opinion but are unknown to those reading or hearing it"—which is precisely what Schiffman is doing by pointing to this "study"—she has squarely entered the realm of actionable "mixed opinion." Davis v. Boeheim, 22 N.E.3d 999, 1004 (NY 2014); Eshelman v. Puma Biotechnology, Inc., 2018 WL 11411207, at *7 (E.D.N.C. Oct. 29, 2018), aff'd, 2 F.4th 276 (4th Cir. 2021).

The '480 Patent. Schiffman's reply also raises new arguments and introduces new inaccuracies concerning U.S. Patent No. 6,998,480 ("'480 Patent"). In its opposition, Heartland argued that Schiffman could not reasonably rely on the 1987 excerpt to establish the presence of S6A in Splenda as it is sold today. As Schiffman's own May 2023 Article cited the '480 Patent, which described technological improvements since 1987 in how sucralose is manufactured and purified, Schiffman was aware the composition of

manufactured sucralose changes over time. Dkt. 20 at 8 n.4. In her reply, Schiffman does not dispute that the '480 Patent does describe such technological improvements, but instead newly argues that the '480 Patent, like the 1987 excerpt, contradicts Heartland's "own representations made to the U.S. Government" because it "identifies [S6A] as an impurity in Splenda." Dkt. 21 at 5 (citing '480 Patent at col. 17, ll. 25-34²). There is no reason why Schiffman could not have relied on the '480 Patent for this point in her motion. But, even if the Court were to consider this belated argument, it fails because Schiffman mischaracterizes the patent's disclosures, misattributes its authorship to Heartland, and fails to explain how the '480 Patent, filed in 2002, relates to Splenda today.

The lines of the '480 Patent cited in Schiffman's reply do **not** establish that S6A is an impurity in sucralose. Those lines describe Figure 9 of the '480 Patent, a table listing the results of testing several samples of sucralose purified using the patented method for various potential impurities. *Id.* at Fig. 9. For all samples, the level of all potential impurities other than water was reported as "<0.01," indicating that the "resolution of the test[s]" used did not permit detection below that limit, *id.* at col. 17, ll. 41-45, meaning the amount was less than 0.01%—down to and including zero. The portion of the patent cited by Schiffman concerns a calculation by the drafter in which all potential impurities less than 0.01% were "rounded" up to 0.01%. *Id.* at col. 17, ll. 22-45. Clearly, the patent drafter was attempting to show that the patented method achieved a great level of purity even in a worst-case scenario, but Schiffman reports it to this Court as a fact.

Moreover, Schiffman's reference to the patent as the "TCH Patent," like her reference to the 1987 petition as the "TCH Petition," is misleading, as the '480 Patent was **not** authored or submitted by Heartland. *Id.* at p.1 (identifying Tate & Lyle Public Limited Company as assignee).

² Although Schiffman did not attach the ''480 Patent to her reply, Heartland notes that it is available at https://patents.google.com/patent/US6998480B2.

Finally, Schiffman's argument again assumes the cessation of all progress in the manufacture of sucralose in either 1987 or, now, 2002. This patent was filed in 2002, over 20 years ago and years before Heartland began selling Splenda. It thus has nothing to say about the presence of S6A in Splenda today. *Cf.* Dkt. 20 at 9 (pointing out, with respect to the 1987 petition to the FDA, that "a chemical analysis of a pre-commercial, laboratory sample of sucralose from 35 years ago is not probative of the purity of the commercially manufactured sucralose contained in Splenda today"). As the '480 Patent does not affirmatively report any actual detection of S6A in sucralose, cannot be attributed to Heartland, and cannot be assumed to reflect the current composition of Splenda, Schiffman cannot rely on it, even belatedly, to support dismissal of Heartland's claims.

* * * * *

By trying to add yet more extraneous purportedly factual material to the record in her reply brief, Schiffman has demonstrated again why this case is not subject to dismissal as a matter of law under Rule 12(b)(6). The motion to dismiss should be denied.

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the page- and word-count limitations in Local Rule 7.3(d)(1).

/s/ Gloria Park Gloria Park

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing document has been duly served upon all counsel of record for the parties on.

This, the 5th day of March 2024.

/s/ Stephen W. Petersen
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